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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/566,214 | 01/27/2006 | Hisashi Nagamoto | 05 273.0099 | 1021 |
| 22852 | 7590 | 02/19/2010 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | EXAMINER PAGONAKIS, ANNA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1628 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,214

Applicant(s)

NAGAMOTO ET AL.

Examiner

ANNA PAGONAKIS

Art Unit

1628

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 14, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-14 and 16-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 11/13/2009, has been received and entered into the present application. Accordingly, prosecution has been reopened.

The Declaration of Hisashi Nagamoto filed 11/13/2009 has been received and considered.

Applicant's arguments, filed 11/13/2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Urashima et al (WO 97/13515, provided by Applicant) as evidenced by Fox et al. (Sem. in Arthritis Rheum, Nov. 1984).

Urashima et al teaches the treatment of Sjogren's syndrome and "dry eye" syndrome with administration of the elected compound (page 6, lines 3-8 and page 7, lines 4-9).

Fox et al. teach that Sjogren syndrome is an autoimmune condition in which dry eyes (keratoconjunctivitis sicca) and dry mouth (xerostomia) result from lymphocytic infiltration of lacrimal and salivary glands (lines 1-2 of abstract).

Though Urashima et al is silent as to the effect of the elected compound to accelerate salivation, the administration of the claimed compound to patients suffering from Sjogren's syndrome is expected to necessarily have the claimed effect on acceleration of salivation, whether recognized by the author or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstance or, in the present case, the same host. Please reference MPEP 2112.

Moreover, the very teaching of the identical compound to overlapping patient populations (i.e. patients suffering from Sjogren's syndrome) necessarily means that the claimed acceleration of salivation is necessarily present, whether recognized by the author or not. As stated *supra*, products of identical composition cannot exert mutually exclusive properties. Please reference MPEP 2112 and *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. and Inter. 1993).

Response to Applicant's Remarks

Applicant has submitted the Declaration by Hisashi Nagamoto which allegedly demonstrate that oral administration of the elected carbostyryl compound does not successfully treat dry eye. Therefore, Applicant concludes that the declaration in addition to the instant specification is not present in the teachings of Urashima. Applicant further alleges that this position is also supported due to the lack of stimulation at the muscarine M3 receptor.

As noted in the above rejection, Urashima et al. and the instant claims are drawn to the administration of rebamipide to those suffering from Sjogren's syndrome. Therefore, overlapping patient populations exist. Though the acceleration of salivation itself was not recognized as a pharmacological

effect of administering the elected compound, such an effect would have necessarily occurred with administration of the elected compound to identical patient populations (i.e. Sjogren's syndrome patients).

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642